


IMPLEMENTATION CHECKLIST

ISO 13485:2003

Quality Management Systems – Requirements for regulatory purposes

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| Company | Auditor | Date of Review |
|---------|---------|----------------|

| <u>ISO13485</u> | <u>Paragraph & check point(s)</u> | <u>Objective evidence</u> |
|-----------------|---|---------------------------|
| 4 | Quality Management System | |
| 4.1 | General requirements | |
| | 1.1 How does the organization, | |
| | <ul style="list-style-type: none"> a) identify the processes needed for the QMS (see section 7: Customer related processes, Design and development, Purchasing, Production and service provision); b) determine the sequence and interaction of these processes (e.g. by use of algorithms, flow charts, process mappings, descriptions); c) determine criteria and methods required to ensure the operation and control of these processes are effective; d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; e) measure, monitor and analyze these processes; f) implement action necessary to achieve planned results and maintain the effectiveness of these processes; | |
| | 1.2 How does the organization maintain the effectiveness of its established QMS (i.e. internal audits, management review, corrective and preventive actions, and independent external assessments). | |
| | 1.3 What evidence is available that outsourced processes that affect product conformity with requirements are controlled by the organization (see section 8.5.1)? | |

| ISO13485 | Paragraph & check point(s) | Objective evidence |
|---|---|--------------------|
| 4.2.2 | Quality manual | |
|  | 3.1 Verify that the quality manual includes, <ul style="list-style-type: none"> a) the scope of the QMS, b) details of, and justification for, any exclusions and/or non-application (see 1.2); c) the documented procedures established for the QMS, or reference to them; d) a description of the interaction between the processes of the QMS; | |
| | 3.2 Verify that the quality manual outlines the structure of the documentation used in the QMS. | |
| | 3.3 Verify that the quality manual is established and maintained. | |
| | 3.4 Verify that the scope of the QMS, including any exclusion, covers the organizations business. | |
| 5.3 | Quality policy | |
| | 8.1 Verify that the quality policy is signed by top management. | |
| | 8.2 Verify that other organizational policy documents are consistent with the quality policy and appropriate to the purpose of the organization. | |
| | 8.3 Verify that the policy includes a commitment to comply with requirements and to maintain the effectiveness of the QMS | |
| | 8.4 Interview personnel at appropriate levels in the organization what the quality policy is and how they contribute to attaining its objectives. | |
| | 8.5 Verify that these communications (8.4) are consistent with other internal/external communications (clause 5.1.a, 5.5.1, 5.5.3, 6.2.2.d, 6.3c, 7.2.3, 7.3.1 and 7.4.2). | |
| | 8.6 Interview top management how the quality policy is reviewed, revised, and controlled (per clause 4.2.3). | |
| 6.2.2 | Competence, awareness and training | |
| | 19.1 How does the organization identify competency needs for a specific position, a family of positions (such as operators or managers) or a cluster of jobs performing activities affecting product quality? | |
| | 19.2 What training is provided to satisfy these competencies needs? | |
| | 19.3 How does the organization evaluate the effectiveness of the training provided (polling the trained employee, evaluating work performance)? | |

19.4 *Interview personnel at appropriate levels in the organization to ensure that they are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.*



19.5 *Verify adequacy of employee education / training / skills / experience records.*

6.3**Infrastructure**

20.1 *How does the organization identify, provide and maintain,*

- a) *buildings, workspace and associated utilities (storage areas, handling facilities, laboratory, test buildings, office space);*
- b) *process equipment (both hardware and software, planned maintenance, cleaning systems);*
- c) *supporting services (such as transport or communication, emergency services, back-up facilities, disaster recovery plans);*

to achieve the conformity to product requirements?

20.2 *Verify that documented procedures are available for the maintenance, cleaning and checking of all equipment used in production, and for the control of the work environment.*

20.3 *Verify that the necessary adjustments and maintenance intervals are established.*

20.4 *Verify that the documented requirements for maintenance activities include a frequency.*

7.4**Purchasing****7.4.1****Purchasing process**

33.1 *How does the organization control the purchasing processes to ensure that purchased product conforms to specified purchase requirements?*

33.2 *Verify that the type and extent of control is based on the effect on subsequent realization processes or the final product.*

33.3 *What evidence is available that the organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements?*

33.4 *How does the organization determine criteria for selection and periodic (re) evaluation?*



33.5 *Verify that records of results of evaluations and follow-up actions are maintained.*

33.6 *How does the organization communicate the results of evaluations within the organization?*

ISO13485**Paragraph & check point(s)****Objective evidence**

- 33.7 *Where being ISO 9001 / 13485 certification is a selection criteria, does the scope cover the product / service bought by the organization?*